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14
15 UNITED STATES DISTRICT COURT
16
17 NORTHERN DISTRICT OF CALIFORNIA

18
19 In re RIGEL PHARMACEUTICALS, INC.) No. 3:09-cv-00546-JSW
20 SECURITIES LITIGATION)
21 _____)
22 This Document Relates To:)
23 ALL ACTIONS.)
24 _____)
25 PLAINTIFF'S OPPOSITION TO RIGEL
26 AND INDIVIDUAL DEFENDANTS'
27 MOTION TO DISMISS CONSOLIDATED
28 AMENDED COMPLAINT AND
UNDERWRITER DEFENDANTS' JOINDER
THERETO

1 DATE: April 9, 2010
2 TIME: 9:00 a.m.
3 COURTROOM: The Honorable Jeffrey
4 S. White

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SUMMARY OF THE ARGUMENT

1 Plaintiff's well pled complaint alleges with particularity that defendants knowingly made
 2 materially false and misleading statements regarding R788, Rigel Pharmaceuticals, Inc.'s ("Rigel" or
 3 the "Company") lead drug candidate for the treatment of rheumatoid arthritis ("RA"), as well as its
 4 prospects for a partnership to commercialize the drug in violation of the Securities Exchange Act of
 5 1934 ("1934 Act"). 15 U.S.C. §78u-4(b)(1); *Berson v. Applied Signal Tech., Inc.*, 527 F.3d 982 (9th
 6 Cir. 2008); *Tellabs v. Makor Issues & Rights, Ltd.*, 551 U.S. 308 (2007). The CAC also sufficiently
 7 alleges that the February 2008 offering contained false statements regarding R788, for which the
 8 defendants are liable under the Securities Act of 1933 ("1933 Act").¹ *In re Intrabiotics Pharm., Inc.*
 9 *Sec. Litig.*, No. C 04-02675 JWS, 2006 U.S. Dist. LEXIS 15753 (N.D. Cal. Jan. 23, 2006).

10 On the first day of the Class Period, 12/13/07 (and thereafter) defendants touted "impressive"
 11 and "statistically significant" results from R788's Phase IIa RA clinical trial. ¶¶6, 60-62, 159, 165.
 12 These statements were false because the results were not statistically significant under basic
 13 statistical principles. ¶¶68-81. Further, defendants presented combined data from patients in the
 14 U.S. and Mexico concealing a country interaction which rendered their statements misleading. ¶¶8,
 15 69-77, 82-90, 161(a), 167(a). Defendants also trumpeted R788's "good" safety profile and
 16 "tolerability." ¶¶60-62, 159, 165. Defendants knew, but concealed from investors, additional
 17 adverse events that increased the risk that Rigel would not obtain a partnership or commercialize the
 18 drug, including a dose-dependent increase in average blood pressure, a potential "show stopper."
 19 ¶¶9, 19-20, 90-91, 104, 120-125, 132-141, 173.

20 Rigel's stock price tripled on defendants' 12/13/07 statements, paving the way for Rigel to
 21 raise \$127.5 million in a 2/08 offering (the "Offering"). ¶¶67, 129. On 10/27/08, when additional
 22 adverse side effects and efficacy data were disclosed, Rigel's stock price plummeted 38%. ¶¶129,
 23 185. Nonetheless, Rigel stock continued to trade at inflated levels as defendants falsely assured
 24 investors that a partnership remained "on track." ¶¶176-177. On 2/3/09, defendants revealed there
 25 would be no partnership until R788 demonstrated further results. ¶¶175-80.

26
 27 ¹ "CAC" refers to the Consolidated Amended Complaint for Violations of the Federal
 28 Securities Laws, dated 1/27/10 ("CAC") (Doc. 59). All "Doc." references are to the Court's
 Electronic Case Filing system. All paragraph ("¶") references are to the CAC.

1 **I. Introduction**

2 This case involves materially false and misleading statements about the efficacy and safety
 3 results of R788, Rigel's "lead [drug] candidate" and Rigel's prospects for a partnership to
 4 commercialize the drug. ¶¶1, 3, 50. R788 was being developed as an oral drug to treat RA, without
 5 "the significant potential side effects and other shortfalls, including gastrointestinal complications
 6 and kidney damage" patients endured with other treatments. ¶51. Rigel's investment thesis
 7 depended on "very robust efficacy results and [a] strong dose response." ¶72. On the first day of the
 8 Class Period (12/13/07 to 2/3/09), defendants' message to investors was clear: "**significant ACR**
 9 **scores** and **good tolerability** observed in [the Phase IIa R788] clinical trial, and the further benefit of
 10 oral delivery may make R788 a favorable alternative to the currently marketed biological agents";
 11 "[t]hese very important clinical trial **results are a major milestone** for Rigel"; and "this study fairly
 12 establishes **with certainty** that this drug is **effective** in [RA]." ¶1; 60; *see also* ¶61-62.² Defendants
 13 backed up their statements with false data that purportedly supported statistically significant results
 14 and "good tolera[nce]," including p-values, response rates and safety results. ¶¶60-62. Rigel's stock
 15 price more than tripled in a single day with analysts reporting that "R788 Shows Home Run
 16 Efficacy" and "no evidence of dose dependent hypertension." ¶¶63-65.

17 Defendants, by way of the instant motion, do not meaningfully challenge the falsity of the
 18 reported efficacy results other than to rehash the tired notion that they can't figure out what is
 19 alleged to be false. A plain reading of the CAC, puts this notion to rest. *Compare, e.g.*, Rigel and
 20 Individual Defendants' Motion to Dismiss Consolidated Amended Complaint, dated 2/16/10
 21 ("MTD") (Doc. 63) at 15:21-25 (plaintiff does not allege that the p values were false) *with e.g.* ¶¶76

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 24 ² The officer defendants are James Gower ("Gower") (Chairman of the Board of Directors
 25 and CEO), Ryan Maynard ("Maynard") (CFO), Donald Payan ("Payan") (EVP of research),
 26 Raul Rodriguez ("Rodriguez") (EVP and COO), and Dr. Elliot Grossbard ("Grossbard") (EVP
 27 and Chief Medical Officer). ¶¶29-33. The director defendants are Jean Deleage, Bradford
 28 Goodwin, Gary Lyons, Walter Moos, Hollings Renton, Peter Ringrose and Stephen Sherwin.
 ¶¶35-41. The underwriter defendants are Credit Suisse Securities (USA) LLC, Oppenheimer &
 Co. Inc., Thomas Weisel Partners LLC and Jefferies & Company, Inc. ¶¶43-46. Unless
 otherwise specified, the term "defendants" will refer to the officer defendants and Rigel.

1 (“false p-values”) ¶81 (p-values reported are false); ¶¶192, 196.³ All of defendants’ statements
 2 regarding R788’s effectiveness and statistical significant dose response were false and misleading
 3 for the same reason – the known results of the clinical trial undermined their statements. Indeed, not
 4 only does the CAC detail Stanford University Professor (Emeritus) of Biostatistics, Dr. Daniel A.
 5 Bloch’s (“Dr. Bloch”) analysis of defendants’ violations of statistics to report unsupported efficacy
 6 results, defendants belatedly admit a known country interaction that rendered the results unreliable.
 7 ¶71. Despite defendants’ creative efforts to spin the CAC as alleging flaws with “study design” or
 8 “data interpretation,” the CAC actually alleges that defendants made false and misleading statements
 9 about the efficacy results of the clinical trial under basic tenets of statistics; these allegations must be
 10 accepted as true. *In re Gilead Scis. Sec. Litig.*, 536 F.3d 1049, 1055 (9th Cir. 2008).

11 Likewise, defendants concede that the safety results of the R788 clinical trial were not
 12 completely disclosed on 12/13/07 when defendants told investors that the results demonstrated
 13 “good tolerability” and revealed safety data in support thereof. ¶60 at 15:7. The CAC alleges with
 14 particularity defendants’ affirmative statements and omissions of material adverse safety results,
 15 namely a dose dependent increase in average hypertension that defendants would later concede was
 16 a significant side effect. *See, e.g.*, ¶¶93, 99. The concealed information rendered investors unaware
 17 of (a) the known material risk that a partner would not fund or delay funding of the development of
 18 R788 – the central premise of Rigel’s entire investment thesis; and (b) increased regulatory risk that
 19 would require larger and longer clinical studies; and (c) adverse safety results which would be
 20 described as potentially “a show stopper.” ¶¶102-104. While defendants discount the undisclosed
 21 safety data as “mild”, the study results they point to do not make that distinction. MTD at 17:23-28
 22 (citing Declaration of William S. Freeman in Support of Rigel and Individual Defendants’ Motion to
 23 Dismiss Consolidated Amended Complaint (“Freeman Decl.”), Ex. M at 3315, Table 4 – showing
 24 overall incidence of “**adverse events**”). Further, the market’s negative reaction to adverse safety data
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 27 ³ Compare also MTD at 16 (raw patient data could not be false) with ¶¶82-90 (presentation
 28 of combined Mexico/U.S. data concealed material risk that R788 was not as effective as
 defendants touted); MTD at 11:20-21 (defendants did not tout dose response) with ¶¶61 (at
 17:3), 64, 66 (defendant Grossbard touting “a good dose response”).

1 in a sister study released weeks prior to the Class Period reinforces the known importance of the
 2 concealed information. ¶¶54-59. Regardless, the effect of the concealment of R788's toxicity
 3 results created an impression of R788 that was far more promising than the facts known to
 4 defendants supported at the time of their statements. *See, e.g.*, ¶64 ("It is hard to imagine better
 5 results.").

6 Defendants' glowing reports of R788's clinical results on 12/13/07 more than tripled its stock
 7 price and allowed Rigel, just six weeks later, to tap the market to the tune of \$127.5 million and
 8 avoid insolvency. ¶¶12, 15, 67, 128.⁴ Later in February and July 2008, defendants kept Rigel's
 9 stock price inflated by continuing to tout the results of the R788 clinical trial, including its
 10 "unprecedented numbers," "profound efficacy result," and good "safety profiles" – statements that
 11 were false for the identical reasons that defendants' 12/13/07 statements were false. ¶¶159, 165.

12 On 10/27/08, one shoe dropped, when defendants belatedly revealed the data for the U.S. and
 13 Mexico separately (*i.e.*, the country interaction data), undermining the previously touted efficacy
 14 results. ¶70. On this news, Rigel's stock plummeted 38% in a single day. ¶¶18, 185. Rigel's stock,
 15 however, remained artificially inflated because even in the face of their disclosures, defendants
 16 claimed they were "still on track" for a partnership to develop R788. ¶176-177. Untrue – Rigel was
 17 not "on track" for a partnership because before making a \$100+ million commitment to develop
 18 R788 any potential partner would have been informed by due diligence (*i.e.*, the actual results) that
 19 R788 had not demonstrated the efficacy that would support such a commitment. ¶¶178-179. This
 20 became evident three months later, when the other shoe dropped – Rigel admitted that any
 21 partnership discussions would be delayed until "after results" from additional studies of R788. ¶180.
 22 On this news, Rigel's stock dropped another 9.3% to \$6.50 per share, 75% below its offering price of
 23 \$27 per share, only a year earlier. ¶¶20, 180, 187.

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⁴ The February 2008 Offering was intended to raise \$135 million but only raised \$127.5 million.

1 **II. Summary of False and Misleading Statements**

2 **Rigel's Claimed Statistically Significant Efficacy Results Were False:** On 12/13/07, Rigel
 3 issued a press release touting "Rigel's R788 Demonstrates Significant Improvement in Rheumatoid
 4 Arthritis in Phase 2 Clinical Study; Achieves Statistically Significant ACR20, ACR50 & ACR70
 5 Results" including the following efficacy results:

# of Patients	Placebo	50MG	100MG	150MG
	47	46	49	47
ACR20	18 (38%)	15 (33%)	32 (65%) (p=.008)	34 (72%) (p<.001)
ACR50	9 (19%)	8 (17%)	24 (49%) (p=.002)	27 (57%) (p<.001)
ACR70	2 (4%)	1 (2%)	16 (33%) (p<.001)	19 (40%) (p<.001)

¶¶60, 69. During a conference call the same day, defendants described these results as "highly statistically significant," "impressive," and stated that the study "establishes with certainty that this drug is effective." ¶61. Defendants continued to tout the efficacy results in the Offering, a 2/11/08 conference and a 7/8/08 conference. ¶¶150-151, 159, 165.⁵

The actual results of the trial, available to defendants (but withheld from investors), demonstrate the falsity of each of defendants' statements regarding whether R788, in fact, worked.

¶¶70, 91. Each of defendants' statements stems from understated p-values that falsely portrayed R788 as achieving statistically significant improvement against placebo, when it did not. ¶74. The proper application of basic statistics, as explained by Dr. Bloch, evidences that the p-values were much higher than defendants touted, and thus the "*success rates between either of the high dose*

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 23 ⁵ Defendants assert incorrectly that Maynard and Payan did not make or prepare any of the
 24 alleged fraudulent statements and thus, cannot be liable. MTD at 12 n.7. However, both
 25 Maynard and Payan attended the 12/13/07 conference call, where Gower and Grossbard made
 26 statements that Maynard and Payan knew were false and misleading. ¶61-62; Freeman Decl., Ex.
 27 C. Because Maynard and Payan failed to correct statements they knew to be false and
 28 misleading, they are liable for those statements. *Barrie v. Intervoice-Brite, Inc.*, 409 F.3d 653,
 656 (5th Cir. 2005) ("Where it is pled that one defendant knowingly uttered a false statement and
 the other defendant knowingly failed to correct it, . . . the fraud is sufficiently pleaded as to each
 defendant."); *accord McGuire v. Dendreon Corp.*, No. C07-800 MJP, 2008 U.S. Dist. LEXIS
 98773, at *25-*26 (W.D. Wash. Dec. 5, 2008). For the same reason, because the subject of the
 12/13/07 conference call was the false and misleading efficacy and safety data contained in the
 press release issued that day, these defendants are also liable for statements in the press release.

1 **groups and Placebo are not statistically significantly different" and the p-values "are false and**
 2 **misleading."**⁶ ¶81. Indeed, the CAC details that defendants violated basic statics, presenting a far
 3 rosier picture of R788's efficacy than the results supported by: (a) improperly pooling the data from
 4 the U.S. and Mexico before analyzing it (¶¶75-77); (b) employing an improper statistical test for
 5 such a small study (¶¶78-79); and (c) failing to account for the multiple comparisons problem (¶¶80-
 6 81).

7 On 12/13/07 defendants also reported "key safety results" setting out select adverse events
 8 and represented that there was "good tolerability observed in this clinical trial." ¶60 at 15:7, 16:2-
 9 17. Defendants stated that the "most common clinically meaningful adverse events . . . were dose-
 10 related neutropenia, mild elevations of liver function tests, and gastrointestinal ("GI") side effects."
 11 ¶60 at 15:25-26. Further, "[t]he incidence of reported moderate hypertension was quite low." ¶61 at
 12 17:13. On 2/11/08 and 7/08/08, defendants continued to tout the safety results of the R788 clinical
 13 trial as "good" and emphasized only "two dose dependent toxicities" – neutropenia and GI
 14 disturbance. ¶¶159 at 51:19, 165 at 55:2-5.

15 At the time of defendants' statements, they knew, but failed to disclose, that (i) there was a
 16 dose-dependent increase in average systolic blood pressure of 2-3mm Hg in 50mg patients, 3-5mm
 17 Hg in 100mg patients, and 8-9mm Hg in the 150mg patients; (ii) 5 patients (not 2) experienced
 18 hypertension, with blood pressure increases as high as 20-30mm Hg; (iii) hypertension was one of
 19 the two most common clinically meaningful drug related adverse events; (iv) 9 patients (not 3)
 20 experienced increased liver enzymes compared to patients taking the placebo; (v) 20 patients (not 15,
 21 as reported on 12/13/07) experienced neutropenia; (vi) 34 patients (not 15) experienced diarrhea; and
 22 (vii) 35 patients (not 15) experienced upper GI side effects. *See, e.g.*, ¶91.

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25 ⁶ On 12/13/07 defendants touted "highly statistically significant" p-values of p=0.008 at
 26 the 100mg dose of and p<0.001 at the 150mg dose, at the primary efficacy endpoint ACR20. In
 27 contrast, the application of "standard statistical methodologies" results in p-values that are more
 28 than 20 times larger at the 100mg dose (p=0.198) and 400 times larger at the 150 mg dose
 (p=0.444). ¶¶74, 81. Likewise, defendants' statements drawn from the false p-values, *i.e.*, that
 the results were "highly statistically significant," "impressive," or established efficacy "with
 certainty" were equally false.

1 **III. Defendants Are Liable for the False Statements in the February 2008
2 Offering**

3 Neither the Private Securities Litigation Reform Act of 1995 (“PSLRA”) nor Fed. R. Civ. P.
4 9(b) applies to claims brought under §§11 and 12(a)(2) of the 1933 Act. *E.g.*, *In re Intrabiotics*
5 *Pharm., Inc. Sec. Litig.*, No. C 04-02675 JWS, 2006 U.S. Dist. LEXIS 15753, at *40-*41 (N.D. Cal.
6 Jan. 23, 2006). Sections 11 and 12(a)(2) therefore “place[] a relatively minimal [pleading] burden
7 on a plaintiff.” *Herman & MacLean v. Huddleston*, 459 U.S. 375, 382 (1983).

8 Indicative of defendants’ tactical blindness to the *actual* allegations in the CAC, they
9 challenge the §§11 and 12(a)(2) claims solely on the grounds that ¶109 of the CAC is a nominal
10 disclaimer of fraud and thus, these claims sound in fraud. MTD at 10:7-17. First, ¶109 does not
11 stand for what defendants propose. Second, the CAC separately pleads defendants’ violations of the
12 1933 Act at ¶¶190-203, as allegations premised only on the negligent failure to disclose material
13 information related to the safety and efficacy results of the R788 clinical trial – that nowhere sound
14 in fraud. Unlike the cases relied upon by defendants, the CAC not only specifically *disclaims*
15 allegations of fraud with respect to the 1933 Act claims, it incorporates *only* the non-fraudulent
16 allegations into those claims. MTD at 10; ¶¶190-203, 222-223, 231, 236. Defendants also identify
17 no averments that sound in fraud. Where, as here, fraud is not an essential element of a claim, Fed.
18 R. Civ. P. 9(b) requires only “averments of fraud” to be pled with particularity. *Vess v. Ciba-Geigy*
19 *Corp.*, 317 F.3d 1097, 1104-05 (9th Cir. 2003). By not addressing plaintiff’s *actual* 1933 Act
20 allegations or explaining why they would not satisfy the notice pleading standard of Rule 8,
21 defendants concede by their silence that the allegations are sufficient. Nonetheless, the 1933 Act
22 claims also satisfy Rule 9(b) as they are pled with particularity.

23 **IV. Defendants Committed Securities Fraud**

24 To assert a violation of §10(b) a plaintiff must “‘plead with particularity both falsity and
25 scienter,’” which are generally strongly inferred from the same facts. *In re Daou Sys., Inc., Sec.*
26 *Litig.*, 411 F.3d 1006, 1014 (9th Cir. 2005).⁷ To plead falsity, plaintiff must identify the statements

27 7 Here and elsewhere, emphasis added and citations omitted unless otherwise stated.
28

1 at issue and “the reason or reasons why the statement is misleading.” 15 U.S.C. §78u-4(b)(1);
 2 *Glenbrook Capital Ltd. P’ship v. Kuo*, No. C07-02377 JSW, 2009 U.S. Dist. LEXIS 30745, at *15
 3 (N.D. Cal. Mar. 30, 2009). To plead scienter, plaintiff must “state with particularity facts giving
 4 rise to a strong inference’ that defendants acted with the intent to deceive or with deliberate
 5 recklessness as to the possibility of misleading investors.” *Berson v. Applied Signal Tech., Inc.*, 527
 6 F.3d 982, 987 (9th Cir. 2008). Here, in accordance with the pertinent case law, this Court’s 12/21/09
 7 Order and the PSLRA, the CAC clearly identifies the false and misleading statements at issue – the
 8 efficacy and safety results of Rigel’s RA clinical study of R788 as well as Rigel’s prospects for a
 9 partnership to fund the development of the drug. It also sets forth particularized facts detailing the
 10 reasons why defendants’ statements were knowingly false and misleading when issued.⁸

11 Rigel was in a race to bring an oral RA pill to market and its investment thesis depended on
 12 achieving Phase IIa results demonstrating both strong efficacy and a benign safety profile. ¶¶51-52,
 13 72, 120-125. Successful trial results would drive future earnings potential and were critical both to
 14 Rigel and its investors. ¶120-125. Without the necessary results, Rigel could neither find a partner
 15 to invest \$100+ million in the development of R788 nor tap investors for the funds necessary to
 16 continue as a solvent company. ¶127-128. However, the results of the trial failed to demonstrate
 17 that R788 was more effective than placebo, in addition to exhibiting troubling side-effects. ¶¶74, 91.
 18 Yet defendants, desperate for cash, shamelessly portrayed R788 as highly effective and touted its
 19 safety profile while concealing key adverse events. *See e.g.*, ¶64 (“[i]t is hard to imagine better
 20 results than Rigel achieved with R788”). As a result, defendants misled the market as to the
 21 expected commercial prospects of R788, including a (1) a larger potential share of the \$13 billion
 22 RA market, and (2) a speedy and lucrative third-party partnership. ¶¶121-124, 132-133.

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⁸ See Appendix of False and Misleading Statements for a chart identifying every statement, alleged to be false and misleading (*i.e.*, in bold italic), and a summary of the reasons why the statement is false and misleading, attached hereto, as Attachment 1.

1 **A. Defendants Knowingly Made Materially False and Misleading**
 2 **Statements About the Efficacy Results of R788**

3 There is no serious question that statements that a company's lead drug prospect worked (like
 4 those at issue here), made when specific facts known at the time show the statement to be inaccurate,
 5 can serve as a basis for a claim of securities fraud. *In re Regeneron Pharm., Inc. Sec. Litig.*, No. 03-
 6 Civ-3111 (RWS), 2005 U.S. Dist. LEXIS 1350, at *62 (S.D.N.Y. Feb. 3, 2005) (quoting *In re*
 7 *Viropharma, Inc., Sec. Litig.*, No. 02-1627, 2003 U.S. Dist. LEXIS 5623, at *23 (E.D. Pa. Apr. 7,
 8 2003) ("It would be a sad day when [a] court could determine that misstatements about whether a
 9 company's primary product worked did not alter the "total mix" of information available in the
 10 market.")); *In re Medimmune, Inc., Sec. Litig.*, 873 F. Supp. 953, 967 (D. Md. 1995) (upholding
 11 statements that "'the results . . . were highly statistically significant'" and "'There's absolutely no
 12 question about efficacy.'"), *compare with*, e.g., ¶61 ("demonstrated statistically significant results"),
 13 ¶61 ("this drug is effective"). Defendants' reliance on *Twinde v. Threshold Pharm., Inc.*, ("*Twinde*
 14 ^I") for the proposition that disclosure of the per-country data prior to 10/27/08 would have been
 15 "overwhelming" is misplaced. No. C 07-4972-CW, 2008 U.S. Dist. LEXIS 58619, at *37-*39 (N.D.
 16 Cal. July 11, 2008); MTD at 16:10-21. Indeed, Judge Wilken's holding that a single undisclosed
 17 non-statistically significant incident of liver toxicity was material, is authority which is not helpful to
 18 defendants. *Id.*; *Twinde v. Threshold Pharm., Inc.* ("*Twinde II*"), No. C 07-4972 CW, 2009 U.S.
 19 Dist. LEXIS 33644, at *35 (N.D. Cal. Apr. 3, 2009), ("Defendants were deliberately reckless in
 20 releasing positive statements . . . when they had material contrary information.").

21 That is precisely why defendants attempt to recharacterize plaintiff's allegations as proposing
 22 an alternate analysis about which "reasonable minds might differ" or that Rigel's "interpretation
 23 finds reasonable support in the data." MTD at 15:12-13. Under the facts pled, there is no
 24 "reasonable support in the data" for the glowing efficacy results defendants touted to the market.
 25 Defendants completely disregard allegations that they were aware of a substantial country interaction
 26 and unbalanced dose distribution between the U.S. and Mexico which marred any reliance on the
 27 combined results. ¶75 (in multi-site clinical trials "site effects and site x treatment interactions
 28 **should always be considered in the analysis of the results.**"); ¶76 ("the ACR rates by Country

1 “easily reveal[] . . . misleading success rates and false p-values.”); see also ¶¶7, 60 at 15:18-20, 61
 2 at 16:26-27, 76-81. Defendants ignore these allegations (and others), when they feign disbelief that
 3 there was knowing or deliberately reckless manipulation of data. MTD at 16:2-3. Compare MTD
 4 15:21-25 with ¶71 (known country interaction); see also *In re Countrywide Fin. Corp. Sec. Litig.*,
 5 588 F. Supp. 2d 1132, 1160 (C.D. Cal. 2008) (complexity of prospectus information coupled with
 6 alleged public misrepresentations, blunted the effect of any disclosures).

7 Likewise, plaintiff takes no issue with the study design of the trial. It is defendants’
 8 misleading statements concerning the study results that are in violation of the securities laws. For
 9 example, hypothetically, defendants could have presented combined country data but employed
 10 proper basic statistics to inform investors that the results were not statistically significant, thereby
 11 ameliorating the misleading nature of the combined results. Instead, defendants affirmatively
 12 proclaimed R788 highly effective supported by false p-values in violation basic statistical principles.
 13 ¶61 at 16:22; 16:26. Thus, unlike the allegations of flaws in “study design and interpretation” or
 14 “design defects” such as those in *Padnes v. Scios Nova Inc.*, relied on by defendants, the CAC does
 15 not question the methodology behind the study. No. C 95-1693 MHP, 1996 U.S. Dist. LEXIS
 16 22858, at *17-*19 (N.D. Cal. 1996); MTD at 14:9-12, 16:10-15. As *Padnes* recognizes, a statement
 17 (such as those here concerning R788’s efficacy results) can be false when issued if there are “facts
 18 tending to seriously undermine . . . the statement.” *Id.* at *17 (citing *In re Apple Computer Sec.*
 19 *Litig.*, 886 F.2d 1109, 1113 (9th Cir. 1989)).

20 Defendants’ claims that the combined country data does not evidence falsity are equally
 21 meritless. MTD at 16:10-21. The CAC pleads with painstaking detail that the combined efficacy
 22 data disclosed on 12/13/07 falsely portrayed an ascending dose response and statistically significant
 23 results. ¶¶74-90. As the chart in ¶70 of the CAC, and appended hereto, as Attachment 2, reflects,
 24 the actual results of the clinical trial (which were known to defendants prior to 12/13/07)
 25 demonstrated that: (i) patients in Mexico in both the active and control group exhibited much greater
 26 response rates than the those in the U.S.; (ii) the distribution by dose was unbalanced – the low dose
 27 was tested exclusively in the U.S. while the high dose was tested nearly exclusively in Mexico; and
 28 (iii) R788 did not exhibit an ascending dose response when active groups were properly compared to

1 the control groups of the same country. ¶¶70, 82-90. For example, on 12/13/07 the combined
 2 results misleadingly informed investors that at ACR20, the 150mg dose was 34% better than placebo
 3 when the per-country data showed that the U.S. patients improved only 16% over placebo and
 4 Mexico patients 21%. ¶85. The distortion exists because nearly all the patients at 150mg were in
 5 Mexico (where response rates were very high) but defendants compared them to the combined U.S.
 6 and Mexico placebo group; roughly half the placebo group was in the U.S., where response rates
 7 were much lower. ¶¶70, 85-86. Similarly, the combined results depicted that the 50mg dose (tested
 8 only in the U.S.) was 5% worse than placebo when in fact it was 9% better. ¶¶87-89.⁹ Dr. Bloch
 9 explained: “These examples illustrate that ***the data from the U.S. and Mexico should not [be]***
 10 ***pooled***, and that proper, overall, analysis must combine the results of pair-wise comparisons
 11 obtained from each country.” ¶89.¹⁰

12 The impression of an ascending dose response – *i.e.*, that the more R788 a patient received
 13 the more they improved – was not supported by the results. The belated 10/27/08 disclosure
 14 indicates that defendants only tested two doses in Mexico, 100 and 150mg, and they performed
 15 almost equally against placebo (20%, 21%). ¶¶85-86. In the U.S., the improvement over placebo at
 16 50, 100 and 150mg were: 9%, 28% and 16% – *i.e.*, the 150mg dose was actually worse than 100mg
 17 by 12%. *Id.* Thus, the ascending dose response was a distortion caused by improperly pooling the
 18 data and was not supported by data from either country. Indeed, in attempting to downplay the
 19 concealed country interaction, on 10/27/08, Grossbard characterized the difference in response rates
 20 between the active and control groups as “all that mattered.” Freeman Decl. at 3, Ex. I. However,
 21 by combining the data, defendants concealed “all that mattered” from investors. ¶89-90.

22 _____
 23 ⁹ Analysts positively described the lack of improvement at 50mg as the “no effect dose”
 24 (*i.e.*, indicative of an ascending dose response at 100mg and 150mg). ¶87.

25 ¹⁰ In its 12/16/09 Questions, this Court asked the parties to address “In light of the fact that
 26 the delay between the active and control groups in both countries was approximately the same,
 27 how do these alleged omissions overstate the dose response and skew the data in favor of R788.”
 28 Doc. 53 at 2. As demonstrated in the CAC, the improvement over placebo for the U.S. and
 Mexico is not “approximately the same.” ¶¶70, 85, 88. More importantly, the CAC
 demonstrates at length how the unbalanced dosing and dramatically different response rates
 (regardless of difference versus placebo) distorted the results in R788’s favor. ¶¶82-90.

1 As a Stanford University Professor (Emeritus) of Biostatistics, an author or co-author of 196
 2 original articles and statistical peer-reviewer for dozens of major journals including *Arthritis and*
 3 *Rheumatism*, Dr. Bloch's expertise as a basis for plaintiff's allegations speaks for itself and is not
 4 seriously challenged by defendants. ¶7; *see* CAC, Ex. A (Bloch Decl.). The CAC's allegations are
 5 to be considered true on a motion to dismiss and defendants' attempt to discredit Dr. Bloch's
 6 analysis for not being peer-reviewed provides no grounds for dismissal.¹¹ Indeed, even if designated
 7 an expert at trial, being peer-reviewed is not a prerequisite to admissibility of his opinions. *Daubert*
 8 *v. Merrell Dow Pharm.*, 509 U.S. 579, 596-7 (1993) (general acceptance (peer review) is not an
 9 absolute prerequisite to admissibility). Grasping at straws, defendants assert that the absence of
 10 allegations in the CAC that the clinical study methodology was inconsistent with Food and Drug
 11 Administration ("FDA") rules somehow renders their statements accurate. MTD at 16:4-9.
 12 Defendants point to no evidence of their FDA compliance. Regardless, not only do FDA guidelines
 13 state that multi-site effects must be accounted for,¹² plaintiff challenges the false and misleading
 14 results, not the methodology of the study.¹³

15 Defendants' statements were materially false and misleading because the efficacy results
 16 were not statistically significant under proper basic statistical analysis, and additionally, defendants
 17 withheld information, such as the country interaction and unbalanced dose distribution, which
 18 "seriously undermine[d]" their statements. *Padnos*, 1996 U.S. Dist. LEXIS 22858, at *17. Having
 19

20 ¹¹ That Dr. Bloch could identify and reverse-engineer Rigel's statistical methodology based
 21 on belatedly revealed data simply speaks to his credentials. *See* MTD at 16:1-4.

22 ¹² The FDA's Notice of "International Conference on Harmonisation; Guidance on
 23 Statistical Principles for Clinical Trials; Availability," states that where efficacy differs by site in
 24 multisite clinical trials, "alternative estimates of the treatment effect, giving different weights to
 25 the centers, may be needed to substantiate the robustness of the estimates of treatment effect."
 26 Declaration of S. Ashar Ahmed in Support of Plaintiff's Request for Judicial Notice in
 27 Opposition to Rigel and Individual Defendants' Motion to Dismiss Consolidated Amended
 28 Complaint and Underwriter Defendants' Joinder Thereto, Ex. 1 at 49589-90.

29 ¹³ Similarly, defendants inaccurately claim that Dr. Bloch challenges the study design.
 30 MTD at 13:9-13. The article in *Arthritis and Rheumatism* stated that the clinical study "would
 31 provide 70% power." Dr. Bloch explained that the study produced only a 50% power under
 32 proper and accepted statistical methods; this is not a challenge to the study design. CAC, Ex. A
 33 at 15.

1 chosen to speak positively about the results of the clinical trial, defendants must do so in a way that
 2 was not misleading. *Brody v. Transitional Hosp. Corp.*, 280 F.3d 997, 1006 (9th Cir. 2002) (a
 3 statement is misleading if it would give a reasonable investor the “impression of a state of affairs that
 4 differs in a material way from the one that actually exists”); *In re Convergent Techs. Sec. Litig.*, 948
 5 F.2d 507, 512 (9th Cir. 1991); *Berson*, 527 F.3d at 987 (9th Cir. 2008).

6 Defendants raise the issue of loss causation solely with respect to the falsity of the reported
 7 p-values, thereby conceding that plaintiff has sufficiently pled loss causation with respect to its other
 8 allegations. MTD at 16:22-17:3. The CAC sets forth a “short and plain statement” under Fed. R.
 9 Civ. P. 8(a)(2) that “provides the defendants with notice of what the relevant economic loss might be
 10 or of what the causal connection might be between that loss and the misrepresentation” as to all of
 11 plaintiff’s allegations. ¶¶181-189; *Dura Pharm., Inc. v. Broudo*, 544 U.S. 336, 347 (2005). Plaintiff
 12 need not allege a disclosure which precisely mirrors the fraud. *Alaska Elec. Pension Fund v.*
 13 *Flowserve Corp.*, 572 F.3d 221, 230 (5th Cir. 2009) (citing *In re Worlds of Wonder Sec. Litig.*, 35
 14 F.3d 1407, 1422 (9th Cir. 1994)). The 12/13/07 reported p-values were the support for defendants’
 15 efficacy claims throughout the Class Period; claims which the market clearly questioned following
 16 defendants’ 10/27/08 disclosure.¹⁴ ¶¶170-174. Indeed, analysts immediately recognized that the
 17 new information was tied to the previously announced efficacy claims. ¶72 (presentation of data
 18 “confounded by” country interaction; country interaction “may have contributed disproportionately
 19 to the benefit observed at the higher doses”); ¶¶73 (unbalanced dose distribution “could skew the
 20 data in favor of R788”); ¶¶170-174.

21 **B. Defendants Knowingly Reported Materially Misleading Safety Results
 22 and Concealed Material Adverse Safety Information**

23 Defendants backed up their statement on 12/13/07 that the clinical trial demonstrated that
 24 R788 was “well tolerated” by admittedly reporting limited safety data on the side effects of R788,
 25 including, liver toxicity, neutropenia, blood pressure, diarrhea and gastrointestinal problems. ¶61 at

26
 27 ¹⁴ Defendants’ argument that plaintiff cannot demonstrate loss causation because Dr. Bloch
 28 only recently calculated the p-values in the CAC is a gross misinterpretation of the relevant legal
 standard. See MTD at 16:22-17:2.

1 17:16; MTD at 17 (Rigel did not “disclos[e] all adverse events (or side effects).”). Thereafter in
 2 February and July 2008 defendants continued to tout R788’s “good safety results.” ¶¶159 at 51:19;
 3 52:7-8; 165 at 55:2-5. Defendants’ misleading statements concerning R788’s toxicity created a
 4 misleading impression in the minds of investors about the likelihood of R788’s commercial viability
 5 and prospects for establishing a partnership to develop R788. ¶¶64-66, 91-113, 117.¹⁵

6 Safety results mattered to investors because the selling point of R788 was that it would not
 7 have the potential side effects exhibited by other RA treatments already on the market. ¶51.
 8 Notably, defendants knew that elevations in blood pressure could be a hurdle for partnership and
 9 commercial viability, a fact established when Rigel’s share price fell 40% after its 11/9/07
 10 announcement that “R788 elevated blood pressure in some patients” in a sister ITP study (an
 11 announcement that was also accompanied by more comprehensive “key” safety results than those
 12 released for the RA study a month later). ¶55 (describing 11/9/07 announcement as “key safety
 13 data”); ¶¶56-57, 97. The market was told in the weeks leading up to the Class Period, that the R788
 14 RA clinical trial at issue here would provide “a good fix on the general effect on blood pressure” and
 15 that defendants would know the “**mean change in blood pressure . . . within a week or two.**” ¶59.
 16 Investors were also led to believe that defendants would perceive results indicating average blood
 17 pressure increase of 5mmHg or more as problematic.¹⁶ *See id.*; MTD at 20 n.12.¹⁷

18 _____
 19¹⁵ Contrary to their cursory arguments, defendants’ statements regarding partnership
 20 discussions being “on track” are false and misleading statements of current business conditions
 21 not subject to PSLRA’s safe harbor. MTD at 13 n.8; *In re Secure Computing Corp. Sec. Litig.*,
 22 184 F. Supp. 2d 980, 990 (N.D. Cal. 2001) (statements that company “was on track to meet
 23 expectations” are “statements of current business conditions” not subject to safe harbor
 24 provision.); *see also In re CV Therapeutics Sec. Litig.*, No. C 03-03709 SI, 2004 U.S. Dist.
 25 LEXIS 17419, at *33 (N.D. Cal. Aug. 5, 2004). Moreover, they knew that in order to get a
 26 partnership R788 would need certain safety and efficacy results which it did not have. ¶¶72,
 103-104, 141. Defendants’ reliance on their “disclosures” is insufficient because they had actual
 27 knowledge that their statements were false and the disclosures were not meaningful. *See, e.g.*,
 28 MTD, Appendix (Doc. 63-1) at No. 4 (“let me remind you that anything we say that looks at
 forward-looking results are obviously subject to the usual caveats.”). *Lormand v. US Unwired,*
Inc., 565 F.3d 228, 244 (5th Cir. 2009) (“Because the plaintiff adequately alleges that the
 defendants actually knew that their statements were misleading at the time they were made, the
 safe harbor provision is inapplicable to all alleged misrepresentations.”).

16 On 12/4/07, defendants also provided further detail of the IPT study, revealing all
 instances where blood pressure increased by 10 mmHg regardless of the clinical diagnosis of

1 There is no dispute that defendants were aware of the actual safety results of the R788 RA
 2 clinical trial depicting greater instances of side effects, including a dose dependent increase in blood
 3 pressure, when they made misleading statements in December, February and July. Defendants try to
 4 minimize the impact of their statements by isolating each piece of safety data and proclaiming that
 5 the additional undisclosed side effects were “mild” and therefore no disclosure was necessary. MTD
 6 at 17-18. They ignore the importance of additional adverse side effects – mild or otherwise – to
 7 Rigel’s investment thesis.¹⁸ To plead materiality, plaintiff need only establish that the information at
 8 issue would “have been viewed by the reasonable investor as having significantly altered the “total
 9 mix” of information made available.” *Basic Inc. v. Levinson*, 485 U.S. 224, 231-32 (1988); *see also*
 10 *SEC v. Phan*, 500 F.3d 895, 908 (9th Cir. 2007) (Materiality is an issue for trier of fact.).

11 Recent controlling authority in the Ninth Circuit confirms that “[d]etermining materiality in
 12 fraud cases “should ordinarily be left to the trier of fact.”” *Siracusano v. Matrixx Initiatives, Inc.*,
 13 585 F.3d 1167, 1178 (9th Cir. 2009). In *Matrixx*, the company claimed that “safety [of the
 14 Company’s drug Zicam] was ‘well established’ by [its] trials” when defendants were aware of one
 15 lawsuit and two research reports linking Zicam to ansonia. In reversing dismissal of the case in the
 16 court below, the Ninth Circuit held that a “reasonable investor” would consider the information
 17 withheld material and rejected defendants’ claim that the omitted information was not “statistically
 18 significant.” *Id.* at 1180-82. Similarly, Judge Wilken in *Twinde I* and *Twinde II* held that defendants
 19 omitted material information when they reported that the company’s drug trial had completed
 20 enrollment, but were aware of, and did not disclose, a ***single non-statistically significant*** incident of
 21 liver toxicity. 2008 U.S. Dist. LEXIS 58619, at *37-*39; 2009 U.S. Dist. LEXIS 33644, at *35.
 22 Here, defendants’ claim that the withheld information related to “mild” side effects is just another

23
 24 hypertension. ¶¶57-58. Yet, nine days later, defendants only revealed a fraction of these results
 in the RA study.

25 Defendants quote this passage at length but offer no plausible competing inference to its
 26 clear meaning: a 5mmHg increase would be a giant red flag. MTD at 20 n.12.

27 Defendants’ assertion that the market knew that additional safety data would be
 28 forthcoming is not in the CAC. Even if the market knew more results were to come, those Rigel
 knew at the time of its statements rendered them false and misleading.

1 way of dressing up the now rejected defense that the information was not “statistically significant.”
 2 MTD at 20. Even if allegations of statistical significance were required to determine materiality, the
 3 purpose of statistical significant argument is to demonstrate a causal connection between the drug
 4 and the observed side effects (*i.e.*, to show they were not due to chance alone). Here, defendants
 5 admit the causal connection, for example, that R788 causes increased blood pressure: “it’s a real
 6 effect. . . . It’s dose dependent. ***There’s no question about it.***” ¶99.

7 Further, defendants’ statements related to R788’s safety results are to be viewed in context as
 8 a totality, not as defendants urge, in piecemeal fashion. *Bourjaily v. United States*, 483 U.S. 171,
 9 179-80 (1987) (“[I]ndividual pieces of evidence, insufficient in themselves to prove a point, may in
 10 culmination prove it.”); *In re Apollo Group Inc. Sec. Litig.*, 395 F. Supp. 2d 906, 920 (D. Ariz. 2005)
 11 (Defendants’ statements as a whole were misleading.); *McMahan & Co. v. Wherehouse Entm’t, Inc.*,
 12 900 F.2d 576, 579 (2d Cir. 1990). Indeed, not only did defendants themselves tout the results
 13 collectively as indicating that the drug was tolerated well and had a good safety profile, analysts
 14 noted the effect of each additional disclosure on the overall safety profile. *See* ¶¶102-104, 107, 111.

15 Courts do not so easily conclude, as defendants urge, that the omitted toxicity results
 16 reflecting that R788 would have “additional regulatory hurdles,” and caused partners to walk away,
 17 can be immaterial as a matter of law. *In re Connectics Corp. Sec. Litig.*, No. C 07-02940 SI, 2008
 18 U.S. Dist. LEXIS 62515, at *22 (N.D. Cal. Aug. 14, 2008) (materially misleading to make
 19 statements about safety of drug candidate without disclosing additional facts that raised serious
 20 questions about safety).

21 The Ninth Circuit has also dispensed with defendants’ conjecture that their statements were
 22 not misleading because investors knew that Rigel was not reporting “mild” side effects. MTD at 16,
 23 20. On 12/13/07 defendants reported “Safety Results” making a notation that diarrhea, GI side
 24 effects and hypertension, were of “severity moderate or greater” without any explanation to investors
 25 as to these terms of art. ¶98. As the Ninth Circuit has opined “***Absent undisputed evidence***” that
 26 ***investors understood the “terms of art” . . .*** we cannot find, as a matter of law, that defendants” made
 27 the requisite disclosures. *Berson*, 527 F.3d at 986-87; *see also* *CV Therapeutics*, 2004 U.S. Dist.
 28 LEXIS 17419, at *22. Here, the facts are even more compelling than those in *Berson* as defendants

1 cannot even explain with the benefit of hindsight that the additional “adverse events” were “mild.”
 2 The article, they cite to, does not refer to “mild” side effects. More importantly, the information was
 3 not inconsequential and analyst reports reflect that the additional safety information had a material
 4 adverse impact on R788’s safety profile. ¶¶102-105, 107-108, 111.

5 Notably, the two cases of hypertension reported by defendants on 12/13/07 cannot be squared
 6 with the belated disclosure on 10/27/08 of five patients experiencing hypertension and that it was
 7 one of “the most common clinically meaningful side effects” of R788 in the clinical trial.¹⁹ ¶¶92-
 8 105. Both defendants and investors were focused on blood pressure effects prior to defendants’
 9 12/13/07 statements as a potentially problematic side effect. ¶¶54-59. When the additional adverse
 10 side effects were disclosed, defendant Grossbard conceded not only that details regarding blood
 11 pressure were “of crushing importance to everybody,” but that blood pressure toxicity would
 12 necessitate additional/longer clinical trials and that it presented a further regulatory hurdle. ¶¶99, 100.

13 The market’s reaction to the “heightened safety” risk disclosures further confirm the
 14 materiality of the withheld information. RBC analyst Kantor downgraded Rigel’s stock and declared
 15 “the perceived risk/benefit ratio has worsened.” ¶¶102-103. The “steep dose related increase in
 16 blood pressure” was a “surprise[]” and would “necessitate a larger and longer Phase II program” and
 17 may limit commercial success. ¶103; *see also* ¶126 (noting securities lawsuit warranted). A Credit
 18 Suisse analyst wrote that the observed 20-30mmHg increase in blood pressure was “probably the
 19 biggest risk to the program” and “could precipitate significant morbidity acutely.”²⁰ ¶104 (also
 20 noting FDA’s “increased scrutiny over cardiac toxicity”); ¶105 (blood pressure toxicity “a risk for
 21 the long term prospects of R788.”) *See also id.*, Freeman Decl., Ex. J at 1 (noting reaction to new

22
 23 ¹⁹ Defendants incorrectly assert that the new negative information about hypertension was
 24 already known to the market because one analyst reported in 12/07 that mild levels of
 25 hypertension were a possibility and because several analysts (who work for the underwriter
 26 defendants in this action) commented that nothing in Rigel’s 10/27/08 disclosures was new or
 27 surprising. MTD at 20 n.15. None of these earlier reports comment on the dose-dependency or
 28 the magnitude of the blood pressure increases. In fact, the 12/13/07 Aberman report notes that
 there was “no evidence of dose-dependent hypertension” based on the defendants’ prior
 disclosures. ¶64.

29
 30 ²⁰ This contradicts defendants’ argument that an increase of 20-30 mmHg “has little clinical
 meaning”; a statement unsupported by the CAC. MTD at 21:1-16.

1 efficacy and toxicity data); Ex. L at 1-2 (“Shares fell sharply, likely due to . . . concerns about
 2 safety” and noting new data gave “more complete toxicity picture.”). The 200% increase in the
 3 Company’s stock price following the 12/13/07 false and misleading disclosures, and the 38% decline
 4 in the Company’s stock price following the disclosure of the previously concealed adverse safety
 5 data on 10/27/08, further confirms the materiality of the concealed information.²¹ ¶¶18, 182, 185;
 6 *No. 84 Employer-Teamster Joint Council Pension Trust Fund v. Am. West*, 320 F.3d 920, 935 (9th
 7 Cir. 2003) (Stock price reaction “further supports a finding of materiality.”).

8 While the discussion above explains that defendants’ parsing of the data is inappropriate and
 9 that defendants’ statements as to the safety results of R788 were material because they failed to
 10 disclose the increased safety risk of the drug threatening Rigel’s investment thesis, out of an
 11 abundance of caution, plaintiff will nonetheless address each omission, in turn:

12 **Blood Pressure.** Defendants’ effort to diminish the import of the increase in average blood
 13 pressure is undermined by their own statements as well as the market’s reaction upon learning of the
 14 previously undisclosed information. *See, e.g.*, ¶103 (analysts noted a “steep dose-related increase in
 15 blood pressure” after the 10/27/08 disclosure causing at least one partner to walk away). The
 16 weakness in their defense is underscored by their assertions that the average blood pressure change is
 17 immaterial because plaintiff does not make similar arguments about average increases in liver
 18 enzymes or neutrophil counts. MTD at 21:24-22:3. The CAC spells out that dose dependent
 19 neutropenia and increased liver enzymes were disclosed on 12/13/07, thereby highlighting
 20 defendants’ omission of the dose dependent increase in blood pressure. ¶¶60 at 15:26; 94-95.

21 **Liver Toxicity.** On 12/13/07, defendants reported a dose-dependent increase in liver
 22 enzymes in three patients (not the actual nine). ¶¶106-109. The six additional cases were patients
 23 that experienced ALT levels that were 1.2 times the upper limit of normal (“1.2x ULN”) whereas the
 24

25 _____
 26²¹ Additionally, the snippets of analyst reports cited by defendants do not reflect an
 27 “untroubled market,” but rather the individual opinion of the specific analyst as to the possible
 future impact of the additional data. *See* MTD at 17 n.10, 18 n.12.
 28

1 three cases reported previously experienced ALT levels that were 3x ULN.²² Contrary to
 2 defendants' contentions that this was not new information, analysts reported surprise by the
 3 information and wrote that it demonstrated "dose-dependent ALT elevations greater than 1.2x ULN
 4 ***at all doses, which confirms R788's association with LFT increases.***" MTD at 18 n10; ¶¶107-108
 5 (12/13/07 data only "suggested" LFT association).

6 **Neutropenia.** On 12/13/07, defendants reported that 15 patients (not the actual 20)
 7 experienced a dose-dependent increase in neutropenia. ¶110. Defendants' contend only that they
 8 made the same disclosures in 12/07 and 10/08 – *i.e.*, the number of patients who experienced
 9 neutropenia who required dose reduction. MTD at 19:1-13. Defendants' omission of five incidents
 10 of neutropenia (whether dose reduction was required or not) made their prior statements misleading;
 11 a fact highlighted by the analysts reaction: "full phase IIa data showed an increase in neutropenia
 12 from previously reported top-line data;" and from the increase incidents of neutropenia and LFTs
 13 that "R788's side effect profile is ***not benign***, as suggested by prior data." ¶¶107-108, 111; Freeman
 14 Decl., Ex. J at 1, 3.

15 **Diarrhea and GI Side Effects.** On 12/13/07, defendants reported 15 patients experienced
 16 diarrhea (not the actual 34) and 15 patients (not the actual 35) experienced GI side effects. ¶¶112-
 17 113. Defendants contend only that the disclosure of moderate to severe incidences on 12/13/07 was
 18 consistent with later disclosures; defendants do not meaningfully address the materially misleading
 19 omission of the additional incidences known at the time of their statements. MTD at 19:13-20.
 20 However, analysts noted the additional incidences, and one of the premises of R788 is that it would
 21 not have the GI side effects experienced with other RA treatments. ¶51. Regardless, as with the
 22 other side effects there is nothing consistent with reporting that R788 was "well tolerated" on
 23 12/13/07 and then disclosing a "heightened adverse safety risk" profile on 10/27/08.

24

25

26 22 Defendants explanation that the three times the upper limit was chosen because it was
 27 level the FDA "recommended," does not explain why just nine days earlier defendants reported
 28 liver enzymes at twice upper limit of normal in the ITP sister study. ¶57; MTD at 18. The
 change in criteria is indicative of defendants' efforts to minimize R788's safety risks.

1 **V. Defendants Acted with the Requisite Intent**

2 In determining whether there is a strong inference of scienter, the court “must consider the
 3 complaint in its entirety” and determine “whether *all* of the facts alleged, taken collectively, give rise
 4 to a strong inference of scienter, not whether any individual allegation, scrutinized in isolation, meets
 5 that standard.” *Tellabs v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 322-23 (2007) (emphasis in
 6 original). “If a reasonable person would deem the inference of scienter cogent and *at least as*
 7 *compelling* as any opposing inference one could draw from the facts alleged.” *Id.* at 317; *see also*
 8 *Bell Atlantic Corp. v. Twombly*, ____ U.S. ___, 127 S. Ct. 1955, 1965 (2007) (rejecting “a probability
 9 requirement” at the pleading stage”).

10 **A. Defendants Had Actual Knowledge of the Falsity of Their Statements**

11 “The most direct way to show both that a statement was false when made and that the party
 12 making the statement knew that it was false is via contemporaneous reports or data, available to the
 13 party, which contradict the statement.” *Nursing Home Pension Fund, Local 144 v. Oracle Corp.*,
 14 380 F.3d 1226, 1230 (9th Cir. 2004). Here, on the first day of the Class Period, defendants had
 15 *actual knowledge* of the results of the clinical trial that directly contradicted their positive statements
 16 regarding safety and efficacy. *In re Nuvelo, Inc. Sec. Litig.*, No. C 07-4056, 2009 U.S. Dist. LEXIS
 17 105212, at *37-*38 (N.D. Cal. Aug. 17, 2009) (access to information informing defendants of a
 18 greater risk of failure of lead drug candidate while trumpeting the clinical trial results sufficient to
 19 allege scienter).

20 Nine days earlier, on 12/4/07 investors were told that “within a week or two” defendants
 21 would know “the mean change in blood pressure” from the clinical trial. ¶59. What defendants
 22 knew, *inter alia*, was that (i) there was a “a dose-dependent increase in average systolic blood
 23 pressure of 3-5mm Hg in 100mg patients and 8-9mm Hg in the 150mg patients” (¶¶9, 91);
 24 (ii) “hypertension was one of the “most common clinically meaningful” side effects of the clinical
 25 trial (¶¶91, 93); and (iii) that some patients experienced blood pressure increases as high as 30mmHg
 26 (¶¶92, 96). Yet, what defendants told the market created an impression that stood in marked contrast
 27 to this knowledge, including that: “[t]he incidence of reported moderate hypertension was quite low”
 28 and that “[t]he most common side effects were neutropenia and gastrointestinal side effects” (not

1 hypertension). ¶61; *see also* ¶64 (“no evidence of dose dependent hypertension”); ¶65 (“good
2 tolerability”).

3 As to the efficacy of R788, not only did defendants have the study results demonstrating that
4 under basic statistical principals R788 did not show statistically significant improvement, but
5 defendant Grossbard admitted to being concerned about and having knowledge of the substantial
6 country interaction. ¶¶70-71. The very country interaction which, when revealed, alerted investors
7 to concerns that that R788 was not as effective as previously touted by defendants. ¶72 (“The main
8 concern is the impact of the Mexican data may have been to overstate the dose response . . . [as]
9 [t]he investment thesis for R788 in RA is based largely on the very robust efficacy results and strong
10 dose response.”); ¶73. No more is required to establish a strong inference of scienter.

11 **B. The Core Operations Inference Bolsters a Finding of Scienter**

12 The Ninth Circuit has held that, even standing alone, management’s role in the business
13 could satisfy scienter where the events were so significant to a business’s present and future
14 revenues it would be ““absurd to suggest”” that management would not have known of them.
15 *Berson*, 527 F.3d at 987; *see also* *Am. West*, 320 F.3d 920. In *South Ferry LP v. Killinger*, 542 F.3d
16 776, 784 (9th Cir. 2008), the Ninth Circuit confirmed that “the core operations inference can be one
17 relevant part of a complaint that raises a strong inference of scienter” and that “in some unusual
18 circumstances, the core operations inference, without more, may raise the strong inference required
19 by the PSLRA.”²³

20 The crux of defendants’ fraud goes to the very heart of Rigel’s business as a clinical-stage
21 drug development company – the safety and efficacy results of R788, its “lead product candidate.”
22 ¶¶2-3, 10, 49-51, 120-132. The defendants were the most senior executives of a Company with a
23 mere 159 employees who’s investment thesis depended on robust safety and efficacy results of
24 R788. *Id.*; *see also* ¶¶10, 29-33, 72, 91, 115, 142-147, 164, 169. The false statements related to its
25 singularly most important drug candidate. At the time of defendants’ statements, Rigel had not

26
27 ²³ The Seventh Circuit agrees, holding, on remand, in *Tellabs* that it was ““exceedingly
28 unlikely” that false statements about the Company’s “most important products” resulted from
“careless mistakes” as opposed to “intent to deceive.” 513 F. 3d at 709.

1 received a single penny from the sale of any drug and thus, defendants were well aware of the
 2 importance of the safety and efficacy results of R788. MTD Appendix at No. 3. The failure of R788
 3 to live up to its hype would have an immediate and devastating effect on Rigel’s ability to raise the
 4 cash necessary to further test and develop the product through a public offering and/or through a
 5 private partnership as well as cause its stock price to plummet as it did when negative “key” safety
 6 results were revealed in late 2007. *See, e.g.*, ¶¶11-13, 55-58, 97, 127-132, 178. Here, Rigel’s
 7 potential partners were, in fact, scared off by the results of the trial, because they, unlike public
 8 investors, were aware of the actual results and had the experience to analyze them. ¶¶102, 103, 178.

9 The facts alleged here – that R788 was the lead drug candidate of a small company –
 10 establish a strong inference of scienter as to Rigel’s top executives. *In re Amylin Pharm., Inc. Sec.*
 11 *Litig.*, No. 01cv1455 BTM (NLS), 2002 U.S. Dist. LEXIS 19481, at *22 (S.D. Cal. Oct. 10, 2002),
 12 *modified on other grounds* (allegations of scienter “more compelling” than not where lack of insider
 13 stock sales was weighed against allegations that “SYMLIN was Amylin’s primary drug candidate
 14 and Amylin is a small biotech company”) (citing *Nathenson v. Zonagen, Inc.*, 267 F.3d 400, 425-26
 15 (5th Cir. 2001)) (officer’s position will support the inference of scienter where the company in
 16 question, “was essentially a one product company”); *see also In re NPS Pharm., Inc.*, No.
 17 2:06-CV-00570, 2007 U.S. Dist. LEXIS 48713, at *22 (D. Utah July 3, 2007) (scienter where
 18 defendants issued false statements about the toxicity of its only drug close to “fruition”).

19 **C. While Not Required, Rigel’s Insider Trading as Well as Defendants’
 20 Additional Motives to Stave Off Insolvency and Receive Additional
 Financial Compensation Add to the Inference of Scienter**

21 The U.S. Supreme Court has stated that “motive can be a relevant consideration, and personal
 22 financial gain may weigh heavily in favor of a scienter inference. The absence of a motive
 23 allegation, however, is not fatal.” *Tellabs*, 551 U.S. 308, 312 (2007). Thus, while not necessary to a
 24 finding of scienter, plaintiff’s motive allegations add additional weight to the scales already tipped in
 25 favor of scienter. Rigel reported just \$44.5 million of cash and \$82.2 million of capital as of
 26 12/31/07, and defendants were aware that Rigel would become insolvent if it did not raise funds.
 27 ¶¶12, 127-129. Indeed, absent the \$127.5 million raised in the Offering, Rigel would have become
 28 insolvent by the end of 3Q08 because it reported a \$99 million net loss in the first nine months of

1 2008 – a powerful motive to commit securities fraud. *Id.*; *see also Howard v. Everex Sys.*, 228 F.3d
 2 1057, 1064 & n.8 (9th Cir. 2000) (“motive to inflate sales to raise financing” circumstantial evidence
 3 of scienter); *Aldridge v. A.T. Cross Corp.*, 284 F.3d 72, 83 (1st Cir. 2002) (scienter where officers
 4 understood the subject of the fraud “was important to their own survival and that of the company”);
 5 *PR Diamonds, Inc. v. Chandler*, 364 F.3d 671, 690 (6th Cir. 2004).

6 In addition, defendants knew that the disclosure of the disappointing efficacy results
 7 (including the country interaction and the unbalanced dose distribution) and adverse toxicity results
 8 of R788 would make it more difficult, if not impossible, to raise additional funds because it would
 9 cause the Company’s stock price to decline. *See, e.g.*, ¶¶11, 13, 129-130. In fact, Rigel’s stock price
 10 declined 40% prior to the Class Period on what analysts attributed as concerns about adverse safety
 11 data related to Rigel’s R788 ITP sister study. ¶¶13, 130-131. Absent the concealment, the
 12 Company’s stock price would not have tripled, and Rigel would not have been able to complete the
 13 offering at \$27.00 per share. ¶15.

14 Defendants try to discount plaintiff’s allegations by contending that courts routinely reject
 15 scienter claims based on a company’s desire to raise capital. MTD at 23. Not true. In *Lipton v.*
 16 *PathoGenesis Corp.*, 284 F.3d 1027, 1038 (9th Cir. 2002), the Ninth Circuit stated that “generalized
 17 assertions of motive, **without more**, [were] inadequate to meet the heightened pleading requirements
 18 of Silicon Graphics.” *Id.* The particularized allegations here, however, are sufficient. *Howard*, 228
 19 F.3d at 1064; *In re U.S. Aggregates, Inc., Sec. Litig.*, No. C01 1688 CW, 2003 U.S. Dist. LEXIS
 20 12168, at *14 (N.D. Cal. Jan. 24, 2003).

21 In fact, Rigel’s February offering is probative of scienter for the additional reason that its
 22 analogous to insider trading. Thus, defendants claim that the “lack of insider sales is powerful
 23 evidence of scienter” is squarely contradicted by the actual allegations pled here. Rigel sold more
 24 than 5 million shares of its stock at the artificially inflated price of \$27 per share as a result of
 25 defendants’ false statements for proceeds of \$127.5 million. ¶¶15, 152, 194. Not only did
 26 defendants Gower, Maynard and Payan authorize this stock sale but Rigel’s illicit proceeds from the
 27 sale allowed all of the defendants to continue to be highly compensated and avoid insolvency. ¶¶11-
 28 12, 15, 29-31, 127-131, 142-147. A “corporate issuer in possession of material nonpublic

1 information, must, like other insiders in the same situation, disclose that information to its
 2 shareholders or re-frain from trading with them.” *McCormick v. The Fund Am. Companies, Inc.*, 26
 3 F.3d 869, 876 (9th Cir. 1994) (collecting cases). A company cannot sell its stock while in
 4 possession of undisclosed material information, “[o]therwise, a corporate issuer selling its own
 5 securities would be left free to exploit its informational trading advantage, at the expense of
 6 investors, by delaying disclosure of material nonpublic negative news until after completion of the
 7 offering.” *Shaw v. Digital Equip. Corp.*, 82 F.3d 1194, 1203-04 (1st. Cir. 1996). This precisely is
 8 what Rigel did here.

9 Rigel’s February Offering corroborates the inference of scienter as to Rigel and the officer
 10 defendants. *In re Cadence Design Sys.*, No. 08-5027 SC, 2010 U.S. Dist. LEXIS 19003, at *28-*28
 11 (N.D. Cal. Mar. 2, 2010) (where accounting manipulations made the difference in making a
 12 company’s quarter, the inference that one officer knew of facts rendering the accounting treatment of
 13 certain deals incorrect was “incompatible with an inference that the other [four officers] lacked
 14 scienter.”).²⁴ The proceeds of the sale are significant (more than Rigel’s combined cash and capital
 15 at year-end 2007) and the timing of the sale is suspicious (on the heels of defendants falsely touting
 16 the significant efficacy results and safety profile of R788 and preventing insolvency). ¶¶12, 15, 60-
 17 62, 127-131, 157.²⁵

18 Further, the lack of insider sales during this critical time when Rigel was looking for a
 19 partner to back R788 are hardly surprising because those sales would have likely been questioned by

20
 21 ²⁴ “Scienter can be established even if the officers who made the misleading statements did
 22 not sell stock during the class period.” *Am. West*, 320 F.3d at 944; *see also Matrixx*, 585 F.3d at
 23 1182 (finding scienter where no allegations of stock sales); *In re Wells Fargo Sec. Litig.*, 12 F.3d
 24 922, 931 (9th Cir. 1993) (insider sales “not required”).

25 Additionally, the February offering hampered defendants ability to sell stock during a
 26 large chunk of the Class Period. *See Am West*, 320 F.3d at 940. (one factor in the scienter
 27 analysis is the ability of a defendant to sell stock). Because the undisclosed offering itself was
 28 material non-public information leading up to its announcement and then, once the offering was
 in place, defendants were subject to a lock-up agreement which precluded trading, the fact that
 there was no individual sales is not dispositive of scienter. *Crowell v. Ionics, Inc.*, 343 F. Supp.
 2d 1, 15 (D. Mass. 2004) (insiders might not sell as many shares as you’d expect because
 “massive trades would expose them to potential criminal liability”). If anything the lock-up
 agreement adds to the inference of scienter. *e.g., In re Entropin, Inc., Sec. Litig.*, 487 F. Supp. 2d
 1141, 1153-54 (C.D. Cal. 2007).

1 potential partners. Indeed, the far more plausible inference is that defendants acted with
 2 deliberateness because the potential for financial success motivated them to keep investors interested
 3 in R788. *See Fla. State Bd. of Admim. v. Green Tree Fin. Corp.*, 270 F.3d 645, 664 (8th Cir. 2001)
 4 (potential for increased compensation “is an important part of the overall picture of scienter”).

5 Defendants’ knowledge that they would receive higher salaries, bonuses and stock option
 6 awards, and that the value of their existing stock options would increase substantially if Rigel
 7 reported positive results from the trial, also adds to the mix of scienter. ¶¶14, 142-147. A strong
 8 correlation between financial results and stock options or cash bonuses supports an inference of
 9 scienter if the allegations show how intimately compensation was tied to the company’s financials.
 10 *Zucco Partners, LLC v. Digimarc Corp.*, 552 F.3d 981, 1004 (9th Cir. 2009) (citing *Am. West*, 320
 11 F.3d at 944); *In re Cornerstone Propane Partners, L.P. Sec. Litig.*, 355 F. Supp. 2d 1069, 1092
 12 (N.D. Cal. 2005) (“[A]llegations about individual defendants’ incentives squarely contribute to a
 13 strong inference of scienter.”). The Company’s proxy statements establish that the compensation of
 14 defendants was based on the clinical development of Rigel’s new product candidates, and that each
 15 received substantial salary increases, bonuses and stock options at the end of 2007 because of the
 16 reported results of the trial and the increase in the price of the Company’s stock at the end of 2007.
 17 ¶¶14, 142-147; *Digimarc*, 552 F.3d at 1004. The value of defendants’ stock options also increased
 18 substantially due to the tripling of Rigel’s stock price caused by defendants’ misleading statements
 19 about the clinical study. ¶146. Plaintiff’s particularized allegations are indicative of scienter
 20 because the amount to far more than the ““routine business objectives”” alleged in *Constr. Laborers*
 21 *Pension Trust of Greater St. Louis v. Neurocrine Biosciences, Inc.*, No. 07CV1111-IEG RBB, 2008
 22 WL 2053733, at *7 (S.D. Cal. May 13, 2008) (citing *Lipton*, 284 F.3d at 1038). Scienter is
 23 sufficiently alleged, as it is here, when there are particularized allegations that the “Company’s
 24 survival” depends on a drug. *CV Therapeutics*, 2004 U.S. Dist. LEXIS 17419, at *32.

25 **D. Defendants Are Control Persons Within the Meaning of §15 of the
 26 1933 Act and §20(a) of the 1934 Act**

27 Both the 1933 Act and the 1934 Act provide for liability to be imposed against those who
 28 exert control over the primary violators of those Acts, and therefore had the power to stop those

1 violations from occurring before investors could be misled or injured. 15 U.S.C. §§77o, 78t; *e.g.*,
 2 *Hollinger v. Titan Capital Corp.*, 914 F.2d 1564, 1575 (9th Cir. 1990); *Howard.*, 228 F.3d at 1065.
 3 The CAC alleges that Rigel, Gower, Maynard, Payan, Grossbard and Rodriguez failed to exercise
 4 the power to prevent the alleged violations of the 1934 Act and that all the Individual Defendants
 5 (except Grossbard and Rodriguez) failed to exercise the power to prevent the alleged violations of
 6 the 1933 Act. *See e.g.*, ¶¶29-33, 35-41, 200, 221, 238. Because defendants' motion to dismiss the
 7 primary violations must be denied as described above, there is a primary violation of the securities
 8 laws from which to premise control liability. *Am. West*, 320 F.3d at 945. Further, plaintiff has
 9 provided a short and plain statement under Fed. R. Civ. P. 8(a)(2) of each of the defendants control
 10 person claims, all that is required under the 1933 and 1934 Act claims. *Cadence*, 2010 U.S. Dist.
 11 LEXIS 19003, at *32-*33 (for control liability to attach actual participation or exercise of control is
 12 not required, generalized descriptions of defendants review or control over the subject matters
 13 misstated are sufficient); *Teamsters Local 617 Pension & Welfare Funds v. Apollo Group, Inc.*, No.
 14 06-2674-PHX-RCB, 2010 U.S. Dist. LEXIS 15232, at *16-*31 (D. Ariz. Feb. 22, 2010) (analyzing
 15 case law and statutory authority and concluding that the notice pleading standard applies for control
 16 person claims under the 1934 Act).

17 **VI. Conclusion**

18 For the reasons set forth above, defendants' motion to dismiss should be denied. If the Court
 19 grants any part of defendants' motion, leave to amend should be granted. *Eminence Capital, L.L.C.*
 20 *v. Aspeon, Inc.*, 316 F.3d 1048, 1051 (9th Cir. 2003).

21 DATED: March 8, 2010

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CERTIFICATE OF SERVICE

2 I hereby certify that on March 8, 2010, I electronically filed the foregoing with the Clerk of
3 the Court using the CM/ECF system which will send notification of such filing to the e-mail
4 addresses denoted on the attached Electronic Mail Notice List, and I hereby certify that I have
5 mailed the foregoing document or paper via the United States Postal Service to the non-CM/ECF
6 participants indicated on the attached Manual Notice List.

7 I further certify that I caused this document to be forwarded to the following Designated
8 Internet Site at: <http://securities.stanford.edu>.

9 I certify under penalty of perjury under the laws of the United States of America that the
10 foregoing is true and correct. Executed on March 8, 2010.

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